

Approval Date MAR 17 2004**FREEDOM OF INFORMATION SUMMARY**

Supplement to NADA 141-087

QUEST Gel

moxidectin

Allows for the addition of new small strongyle species to the indications

Sponsored by:

Fort Dodge Animal Health

FREEDOM OF INFORMATION SUMMARY

1. General Information:

- a. File Number: NADA 141-087
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth Street NW
Fort Dodge, Iowa 50501
Drug labeler code: 000856
- c. Established Name: moxidectin
- d. Proprietary Name: QUEST Gel
- e. Dosage Form: Oral gel
- f. How Supplied: Packaged in ready-to-use Sure-Dial® syringes. Each syringe contains adequate QUEST Gel to treat one horse with a body weight of up to 1150 lbs, or multiple horses and ponies with combined body weights of 1150 lbs.
- g. How Dispensed: OTC
- h. Amount of Active Ingredient: 20 mg moxidectin / mL (2.0 % w/v)
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: The recommended dose level is 0.4 mg moxidectin/kg (2.2 lb) body weight.
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies:
- Large strongyles:**
Strongylus vulgaris - (adults and L₄/L₅ arterial stages)
Strongylus edentatus - (adult and tissue stages)
Triodontophorus brevicauda - (adults)
Triodontophorus serratus - (adults)

Small Strongyles (adults):

Cyathostomum spp., including

Cyathostomum catinatum

Cyathostomum pateratum

Cylicostephanus spp., including

Cylicostephanus calicatus

Cylicostephanus goldi

Cylicostephanus longibursatus

Cylicostephanus minutus

Cylicocyclus spp., including

Cylicocyclus insigne

Cylicocyclus leptostomum

Cylicocyclus nassatus

Coronocyclus spp., including

Coronocyclus coronatus

Coronocyclus labiatus

Coronocyclus labratus

Gyalocephalus capitatus

Small Strongyles:

Undifferentiated lumenal larvae

Encysted cyathostomes:

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids:

Parascaris equorum - (adults and L₄ larval stages)

Pinworms:

Oxyuris equi - (adults and L₄ larval stages)

Hairworms:

Trichostrongylus axei - (adults)

Large-mouth stomach worms:

Habronema muscae - (adults)

Horse stomach bots:

Gasterophilus intestinalis - (2nd and 3rd instars)

Gasterophilus nasalis - (3rd instars)

One dose suppresses strongyle egg production for 84 days.

n. Effect of Supplement:

The supplement provides for the use of moxidectin gel for the treatment and control of adult *Coronocylus labratus*. Also, the label descriptions of the currently-approved small strongyle genera are being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature.

2. Effectiveness:

The use of moxidectin gel for the treatment and control of *Coronocylus labratus* was established in two dose confirmation studies. The first study is study #EQ-92-2 and is described in the original Freedom of Information (FOI) summary for QUEST (moxidectin) Gel dated July 11, 1997. The second study, which is new to this NADA file, is study #0696-E-US-06-00 and is described in the original FOI summary for QUEST PLUS (moxidectin / praziquantel) Gel (NADA 141-216) dated May 14, 2003. In this second study, the effect of the test substance on *Coronocylus labratus* was attributed to the moxidectin component.

3. Target Animal Safety:

This approval does not affect this section of the summary. Please refer to the original NADA 141-087 FOI summary dated July 11, 1997 and the supplemental NADA 141-087 FOI summary dated May 29, 2003.

4. Human Safety:

This drug is intended for use in horses and ponies, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for use in humans. Keep this and all other drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician."

5. Agency Conclusions:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that QUEST Gel, when used under the labeled conditions of use, is safe and effective for the treatment of the gastrointestinal parasites specified on the product label in horses and ponies six months of age and older.

QUEST Gel is labeled for OTC use. Routine deworming of horses is a widely accepted and recommended practice performed by the lay person. A diagnosis of parasite infection prior to deworming is not necessary.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the addition of *Coronocylus labratus* to the indications for which this supplement is approved. This decision is based on the fact that new data was required for this approval.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Moxidectin is under the following U.S. patent number:

U.S. Patent Number
4,916,154

Date of Expiration
April 10, 2007

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton

7440L

NADA 141-087, Approved by FDA

FORT DODGE

QUEST[®]
moxidectin



2% Equine Oral Gel

Contains 20 mg moxidectin/mL
(2.0% w/v)

DEWORMER & BOTICIDE

FOR ORAL USE IN HORSES AND PONIES
SIX MONTHS OF AGE AND OLDER

INDICATIONS

QUEST (moxidectin) 2% Equine Oral Gel when administered at the recommended dose level of 0.4 mg moxidectin/kg (2.2 lb) body weight is effective in the treatment and control of the following stages of gastrointestinal parasites in horses and ponies:

Large Strongyles:

- Strongylus vulgaris* - (adults and L₄/L₅ arterial stages)
- Strongylus edentatus* - (adults and tissue stages)
- Triodontophorus brevicauda* - (adults)
- Triodontophorus serratus* - (adults)

Small Strongyles (adults)

- Cyathostomum* spp., including
- Cyathostomum calinalum*
- Cyathostomum pateratum*
- Cylicostephanus* spp., including
- Cylicostephanus calicatus*
- Cylicostephanus goldi*
- Cylicostephanus longibursatus*
- Cylicostephanus minutus*
- Cylicocycylus* spp., including
- Cylicocycylus insigne*
- Cylicocycylus leptostomum*
- Cylicocycylus nassatus*

- Coronocycylus* spp., including
- Coronocycylus coronatus*
- Coronocycylus labiatus*
- Coronocycylus labratus*
- Gyaloccephalus capitatus*

Small Strongyles:

- Undifferentiated luminal larvae

Encysted cyathostomes

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids

Parascaris equorum - (adults and L₄ larval stages)

Pinworms

Oxyuris equi - (adults and L₄ larval stages)

Hairworms

Trichostrongylus axei - (adults)

Large-mouth stomach worms

Habronema muscae - (adults)

Horse stomach bots

Gasterophilus intestinalis - (2nd and 3rd instars)

Gasterophilus nasalis - (3rd instars)

One administration of the recommended dose rate of QUEST (moxidectin) 2% Equine Oral Gel also suppresses strongyle egg production through 84 days.

QUEST is indicated for use in horses and ponies, including breeding mares and stallions, and foals six months of age and older.

STRATEGIC PROTECTION PROGRAMS

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. For best control of parasites, all horses and ponies should be included in a strategic treatment program, with particular attention given to high performance animals, brood mares, stallions and foals. In foals, initial treatment is recommended at 6 months of age, after which they should be included in a recurrent treatment program. Because QUEST provides effective control of the mucosal stages of small strongyles (encysted cyathostomes), it is useful in reducing the frequency of treatment required for successful strategic equine parasite control. A veterinarian can assist in preparing the best program for your needs.

QUEST 2% Equine Oral Gel when used at the recommended dose rate suppresses strongyle egg production through 84 days following a single oral administration. This residual strongyle control reduces pasture contamination and provides a period of protection from reinfection for horses and ponies maintained on the same pasture.

MODE OF ACTION

QUEST 2% Equine Oral Gel acts by interfering with chloride channel-mediated neurotransmission in the parasite. This results in paralysis and elimination of the parasite. Moxidectin is safe for use in horses and ponies because it does not have the same injurious effect on the mammalian nervous system.

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ADMINISTRATION AND DOSAGE

QUEST (moxidectin) 2% Equine Oral Gel is specially formulated as a palatable gel which is easily administered to horses and ponies. QUEST Gel is packaged in ready-to-use SURE-DIAL® syringes (see diagram of the SURE-DIAL® syringe below). The syringe is calibrated in 50-pound increments, up to 1150 pounds. This enables the administration of the recommended dose level of 0.4 mg moxidectin/kg body weight by choosing a setting consistent with the animal's weight.

HOW TO SET THE DOSE

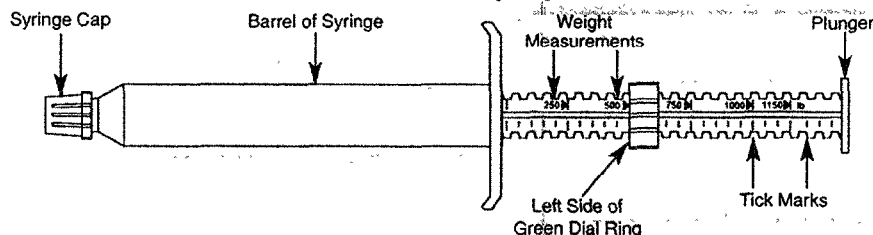
Since the dose is based on the weight of the animal, you need to use a scale or weight tape to find each animal's weight before treating with QUEST Gel. Once the weight is known, set the dose for each horse or pony as follows.

1. Hold the syringe with the capped end pointing to the left and so that you can see the weight measurements and tick marks (small black lines) as shown in the diagram below. Each tick mark relates to 50 lbs. of body weight.
2. Turn the green dial ring until the left side of the ring lines up with the weight of the animal. In the diagram below, the dial ring is set to dose a 500 lb. animal.

HOW TO GIVE QUEST GEL TO A HORSE OR PONY

1. Make sure there is no feed in the animal's mouth.
2. Remove the cap from the end of the syringe. Save the cap for reuse.
3. Place the tip of the syringe inside the animal's mouth at the space between the teeth.
4. Gently push the plunger until it stops, depositing the gel on the back of the tongue.
5. Remove the syringe from the animal's mouth and raise the animal's head slightly to make sure it swallows the gel.
6. Replace the syringe cap.

SURE-DIAL® Syringe



TREATING A SECOND HORSE OR PONY WITH THE SAME SYRINGE

If the first animal you treat weighs less than 1150 lbs., there will be gel left in the syringe. You can use this gel to treat other horses or ponies. To set the next dose, add the weight of the animal you want to treat to the dose setting already on the syringe. For example, if the syringe was first used to treat a 250 lb. animal, the green dial ring is set on 250 lbs. To treat a 500 lb. animal next, move the green dial ring to the 750 lb. marking (250+500=750). You need more than one syringe to treat horses weighing more than 1150 lbs.

Each syringe of QUEST 2% Equine Oral Gel may be used to treat more than one animal especially when dosing ponies and growing and lighter breeds of horses. The table below will help estimate the number of horses or ponies the contents of each syringe will treat.

Age	Ponies			Light Horses			Heavy Horses		
	Weight (lbs)	(kg)	Treated Animals (per syringe)	Weight (lbs)	(kg)	Treated Animals (per syringe)	Weight (lbs)	(kg)	Treated Animals (per syringe)
6 months	200	(91)	5	400	(181)	2	550	(250)	2
9 months	250	(113)	4	500	(227)	2	700	(318)	1
Mature	450	(204)	2	900	(409)	1	1300	(590)	1

* A full syringe plus a portion of a second syringe is required to treat horses weighing more than 1150 lb.

ANIMAL SAFETY

QUEST (moxidectin) 2% Equine Oral Gel can be safely administered at the recommended dose of 0.4 mg moxidectin/kg body weight to horses and ponies of all breeds at least 6 months of age or older. Transient depression, ataxia and recumbency may be seen when very young or debilitated animals are treated. In these instances, supportive care may be advisable. Reproductive safety studies demonstrate a wide margin of safety when the product is used in the treatment of estrual and pregnant mares and breeding stallions.

To report adverse drug reactions or to obtain a copy of the Material Safety Data Sheet (MSDS) call (800)477-1365.

ENVIRONMENTAL SAFETY

Care should be taken to avoid the release of significant volumes of moxidectin into either ground or free-running water since moxidectin may be injurious to aquatic life. SURE-DIAL® syringes and their contents should be disposed of in an approved landfill or by incineration.

PRECAUTIONS

QUEST 2% Equine Oral Gel has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

WARNINGS

Extreme caution should be used when administering the product to foals, young and miniature horses, as overdosage may result in serious adverse reactions. Do not use in sick, debilitated, or underweight animals. Do not use in horses or ponies intended for food.

HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

HOW SUPPLIED

QUEST 2% Equine Oral Gel is available in one syringe applicator size. Each SURE-DIAL® syringe contains 0.4 oz (11.3 g) of QUEST 2% Equine Oral Gel which is sufficient to treat a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb.

NDC 0856-7441-03 — 0.4 oz (11.3 g) syringe - 20 mg moxidectin per mL. Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringes with the cap tightly secured.

U.S. Patent No. 4,916,154

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Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

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Revised January 2004

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QUEST (moxidectin) is effective in the treatment and control of the following stages of gastrointestinal parasites in horses and ponies.

Large Strongyles:

Strongylus vulgaris - (adults and L₁/L₂ larval stages)
Strongylus edentatus - (adults and larval stages)
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Triodontophorus serratus - (adults)

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Cyathostomum calvarium
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Cylicostephanus calceatus
Cylicostephanus plicatus
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Cylicostephanus minutus
Gyalocephalus capitatus

Small Strongyles:

Undifferentiated luminal larvae
 Encysted cyathostomes: Late L₁ and L₂ mucosal cyathostome larvae
Ascaris *Parascaris equorum* - (adults and L₁ larval stages)

Pinworms: *Oxyuris equi* - (adults and L₁ larval stages)

Hairworms: *Trichostrongylus axei* - (adults)

Large-mouth stomach worms: *Habronema muscae* - (adults)

Horse stomach bots:

Gasterophilus intestinalis - (2nd and 3rd instars)
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QUEST suppresses strongyle egg production through 84 days following a single oral administration. This residual strongyle control reduces pasture contamination and provides a period of protection from reinfection for horses and ponies maintained on the same pasture.

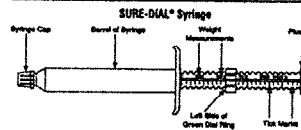
QUEST is available in the SURE-DIAL® syringe for accurate and easy dosing of your animal.

With the SURE-DIAL® syringe you turn the dial ring to the animal's weight. You are now ready to administer the exact amount of QUEST needed for effective parasite control.

Each syringe treats a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

QUEST is indicated for use in horses and ponies including breeding mares and stallions and foals six months of age and older.

Please read entire insert for ADMINISTRATION AND DOSAGE and other important information.



PRECAUTIONS

QUEST Oral Gel has been formulated specifically for use in horses and ponies only. The product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

WARNINGS

Extreme caution should be used when administering the product to foals, young and miniature horses, as over-dosage may result in severe adverse reactions. Do not use in sick, debilitated, or underweight animals. Do not use in horses or ponies intended for food.

HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

STORAGE

Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringes with the cap tightly secured.

U.S. Patent No. 4,916,154

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Fort Dodge Animal Health
 Fort Dodge, Iowa 50501 USA

QUEST[®] GEL
 moxidectin

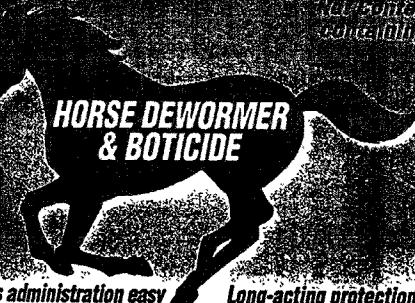
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Lot
 Exp. Date



QUEST[®] GEL
 moxidectin

**HORSE DEWORMER
 & BOTICIDE**



Controls worms and bots **PLUS** small strongyle larvae and eggs SURE-DIAL® syringe makes administration easy Long-acting protection for horses

QUEST[®] GEL
 moxidectin

For horses and ponies including
 breeding mares and stallions

QUEST[®] GEL
 moxidectin

2.5% Equine Oral Gel
 Contains 25 mg
 moxidectin (0.25%) per
 100 mL (4 fl. oz.) of gel
 100 mL (4 fl. oz.) of gel
 contains 2.5 g (0.25%) of
 moxidectin

FORT DODGE

FORT DODGE ANIMAL HEALTH



PROOF OF PURCHASE

Net Contents: One Syringe
 Containing 0.25 g (1/4 oz.)
 moxidectin

QUEST[®] GEL
 moxidectin
 2.5% Equine Oral Gel
 Contains 25 mg
 moxidectin (0.25%) per
 100 mL (4 fl. oz.) of gel
 100 mL (4 fl. oz.) of gel
 contains 2.5 g (0.25%) of
 moxidectin

QUEST[®]
GEL
moxidectin

2% Equine Oral Gel
Contains 20 mg moxidectin/mL (2.0% w/v)
0.4 oz (11.3 g) moxidectin gel

HORSE DEWORMER & BOTICIDE

NDC 0858-7441-03

FOR ORAL USE IN HORSES AND PONIES SIX MONTHS OF AGE AND OLDER

ADMINISTRATION AND DOSAGE: Each syringe treats a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb. Please read entire insert for ADMINISTRATION AND DOSAGE and other important information.

WARNINGS: Exercise caution around the water when administering this product to horses, ponies and miniature horses. Lot overexposure may result in serious adverse reactions. Do not use in sick, debilitated, or underweight animals. Do not use in horses or ponies intended for food.

HUMAN WARNINGS: Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

PRECAUTION: QUEST (moxidectin) Oral Gel has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

STORAGE: Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringe with the cap tightly secured.

NADA 141-087, Approved by FDA

U.S. Patent No. 4,918,154



Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Lot:

Exp Date:

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